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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,566	09/10/2003	Christophe Dupont	2756.001	4677

23405 7590 03/22/2007

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EXAMINER	
BETTON, TIMOTHY E	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,566	DUPONT ET AL.	
	Examiner	Art Unit	
	Timothy E. Betton	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election in the reply filed on 12 March 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Election of Species

Applicant elects the following species for Group I:

I. Species 2 in which part of the non-adhesive surface is covered with active agent.

II.Species 2 c) polypropylenes.

III.Species 1 lyophilization.

IV.Species 2 non-adhesive surface.

V.Species 2 in which the back of the support is covered with a label, which can be peeled off.

Status of the Claims

In the initial Office Action, claims 1-12 were subject to a restriction requirement and an election of species requirement. Claims 14-16 are added by a Preliminary Amendment and are submitted along with the original application. To facilitate prosecution, instant claims 14-16 are deemed as species drawn to a patch comprising a support having electrostatic properties, with individualized or agglomerated particles (the biologically active substance) kept in contact with the non-adhesive surface. For

purposes of this Response, claims 14-16 will be grouped and examined along with claims 1-12 (Group I).

Thus, instant claims 1-12 and 14-16 are pending for examination on the merits.

As stated in MPEP 2164.01(a).

Claim Rejections-35 USC 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transdermal systems such as FINN CHAMBERS®, does not reasonably provide enablement for other transdermal delivery systems or modifications thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. " There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue."

In re Wands , set forth the following eight factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, 1ST paragraph:

1. The nature of the invention;
2. The state of the prior art;

3. The predictability or lack thereof in the art;
4. The amount of direction or guidance present;
5. The presence or absence of working examples;
6. The breadth of the claims;
7. The quantity of experimentation needed; and
8. The level of the skill in the art.

The nature of the invention

The nature of the invention is drawn toward a transdermal device, which under electrostatic properties delivers a biological active substance topically to a subject in need of such therapeutic administration.

The state of the prior art and the predictability or lack thereof in the art

Dupont et al. (PGPUB 20040047902 A1) teach a modification in transdermal system which alleges to facilitate greater therapeutic activity to specified region. The modification comprises a region not coated with adhesive material having a depression forming a hollow. Advantageously, the area defined by the hollow is maintained under vacuum [0051].

The lack of predictability is high due to various susceptibilities of the subject transdermal system modifications and secondly with the susceptibilities of the biologically active substances, which may vary in delivery or potency due to, low epidermal heat conduction, inadequate therapeutic efficacy or toxic concentrations achieved due to pooling (over-pooling) of sweat (containing indeterminate concentrations of biologically active substance) in the hollowed portion of transdermal system [0056].

The amount of direction or guidance present or absent in regard to working examples

The specification contains two example vignettes, which fail to offer adequate direction or guidance commensurate in the scope of the claimed invention. Example 1 specifically only discloses a very general reference to the claimed transdermal system modification. Example 2 discloses an allergenic screening process to cow milk proteins (CMA). In the instant specification, applicants' disclose that all of the subjects exhibited clinical signs suggesting *a possible allergy* to RGO cow's milk proteins (pg 17, lines 6-12). However, the side effects and/or adverse effects of an antiandrogenic transdermal system (exemplary purpose) in comparison to a CMA transdermal system may present side effects greater in magnitude, which in a proper assessment of such administration may suggest, instead, adverse toxicological manifestations. The direction or guidance is absent in regard to working examples commensurate in scope to the claimed invention.

The breadth of the claims, quantity of experimentation, and level of skill in the art

The metes and bounds of the claims are of such a nature as to require a quantity of experimentation that would adequately address the claim of being a 1) ready-to-use, 2) the degree of constancy (reliability and reproducibility), and 3) the guarantee of maintaining allergens of organic origin in their reactogenic states of origin (Specification, page 12). Applicants disclose an invention drawn to overcoming the above three problems, however there is nothing in the specification or the instant claims to at all

suggest being enabled in this basic capacity. One of ordinary skill in the relevant art would instantly recognize the necessity to overcome these three issues in conjunction with the scope of enablement of subject invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

Ardin H Marschel 3/19/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER